K122705

510(k) Summary – HumiCare D900

MAY 2 1 2013

Date prepared	April 12, 2013
Submitter	Christoph Gründler Managing Director Gründler GmbH
Official contact	Jim Cassi V.P., Quality Assurance Americas ResMed Corp. 9001 Spectrum Center Blvd., San Diego CA 92123 USA Tel: +1 858-836-6081 Fax: +1 818-428-6401
Proprietary name	HumiCare D900
Common name	Respiratory Gas Humidifier
Classification	21 CFR 868.5450 Product code 73 BTT
Predicate Devices	K073706, (Fisher & Paykel Healthcare) MR850 Respiratory Humidifier K092256, (Smiths Medical ASD Inc.) Thera-Heat™ Heated Humidifier K983112, (Fisher & Paykel Healthcare) Heated Tubing RT110 as part of MR850 Respiratory Humidifier K100104, (Plastiflex Group NV) Hybernite Rainout Control System
Reason for submission	New device

Intended Use

The Gründler HumiCare D900 system is intended to heat and humidify medical respiratory gases for patients. The device is for use during artificial ventilation or ventilatory support (e.g. invasive ventilation via tracheal tube or cannula), non-invasive ventilation, or respiratory therapy by means of a mask or other patient interface.

Heated breathing circuits are intended to provide warmed and/or humidified breathing gases before entering the patient airway reducing or eliminating water. They are accessories for the Gründler's HumiCare D900. The heated breathing circuits are used for flow rates greater than 3L/min.

The system is for use in hospital/institutional environment or in the home environment by medically trained healthcare users.

Device Description

The HumiCare D900 system is a respiratory gas humidifier according to 21 CER §868.5450. A respiratory gas humidifier is identified by the Food and Drug Administration (FDA) as a therapeutic device that is intended to warm and add humidity.

The HumiCare D900 including heated air tubings is an active heated humidifier which employs a passover humidification via an enhanced surface area for gas/water. The huge gas/water surface area is resulting in an output of gas with a temperature almost identical to that of the water with a relative humidity of 100%.

The principle HumiCare D900 is to direct the gas mixture from the ventilator's outlet into the humidifier's water chamber via air tubing. There it is heated and humidified by means of heated water. A heated inspiratory tube is used to transport the conditioned gas from the water chamber's outlet to the patient.

Depending on the patient interface an inspiratory tube or inspiratory and expiratory tubes can be used for the humidification with HumiCare D900. The inspiratory limb can further include an antibacterial filter with filter heater to reduce condensation. In order to minimize condensation (rain out), both inspiratory and expiratory air tubing can be actively heated therefore temperature sensors are included in the inspiratory and expiratory air tubing.

The HumiCare D900 system consists of a heater base with external power supply, connector cables, a 30day disposable water chambers, heated tubes (inspiratory, expiratory), connection tube, antibacterial filter and filter heater. The 30day disposable water chamber and air tubing circuits are intended for single patient use, with the exception of when an antibacterial filter is incorporated into the circuit allowing multi-patient use of the chamber. The HumiCare D900 heater base and filter heater are intended for multi-patient re-use.

Substantial Equivalence

The new device is substantially equivalent to the above specified predicate devices based on:

- Similar intended use
- Similar operating principle
- Similar Circuit types
- Same fundamental technological characteristics
- Similar performance characteristics.

Design and Verification activities were performed on the HumiCare D900 as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. In particular side-by-side testing demonstrated that the HumiCare D900 essential performance specifications (humidification performance, resistance of the humidifier) are Substantially Equivalent to the predicate devices.

Materials that contact the heated humidified gas pathway are considered to be external communication permanent duration (tissue/bone/dentin). The biological tests for warm wet air path application, in accordance with FDA Guidance #G95-1 were:

- ISO 10993-3 Genotoxicity
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation
- ISO10993-10 Sensitisation and Irritation

The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Heated Humidifier Review Guide (February 1997)

The new device was designed and tested to the following standards:

- FDA-3654 (IEC 60601-1:1988)
- FDA-3654 (IEC 60601-1-2:2007)
- FDA-3654 (ISO 8185:2009)

Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. Performance data demonstrate that the new device is as safe and effective as the predicate devices. Thus the HumiCare D900 system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2013

Gründler GmbH
C/O Mr. Olaf Teichert
Responsible Third Party Official
TÜV SUD America, Incorporated
1775 Old Highway 8 NW
NEW BRIGHTON MN 55112-1891

Re: K122705
Trade/Device Name: HumiCare D900
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: May 3, 2013
Received: May 6, 2013

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
-S FDA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122705

Device Name: HumiCare D900

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Prescription Use ___X___ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122705